Table 2 [Genetic and related effects] of [agent] in humans in vivo

End-point	Test	Tissue	Cell type (if specified)	Description of exposed and controls	Response, significance*	Comments	Reference
DNA damage	• DNA adducts • DNA strand breaks • DNA cross-links • DNA oxidation • Unscheduled DNA synthesis	Bone marrow, lung, buccal, lymphocytes, liver, ovary…	Hepatocyte, endothelial, fibroblast, monocyte, alveolar, mucosa	Industry or occupation; cohort name (e.g. Agricultural Health Study); source of controls; population size; location	+ ($P < 0.01$) (+) +/– – (–)		
Mutation	• Oncogene • Tumour suppressor • Other						
Chromosomal damage	• Chromosomal aberrations • Micronucleus formation • Sister chromatid exchange • Aneuploidy						
DNA repair							

+, positive
–, negative
+/–, equivocal (variable response in several experiments within an adequate study)
* Significance is indicated using asterisks
(+) or (–), positive/negative in a study of limited quality (specify reason in comments, e.g. only a singe dose tested; data or methods not fully reported; confounding exposures, etc.)

Table 3 [Genetic and related effects] of [agent] in experimental animals in vivo

Species, strain, sex	End-point	Test	Tissue	Results	Agent, dose (LED or HID)	Route, duration, dosing regimen	Comments	Reference
Rat F344 male, Mouse B6C3F$_1$ female, etc	DNA damage	• DNA adducts • DNA strand breaks • DNA cross-links • DNA oxidation • Unscheduled DNA synthesis	Liver, lung, bone marrow, leukocyte, spermatocytes, oocytes…	+ (+) +/– – (–) NT	10	Gavage, inhalation, intraperitoneal injection, drinking-water; 14 day; ×1, 1×/day, 1×/wk	Address which other doses had a positive response, if dose–response was evident, etc	
	Mutation	• Mouse spot test • Mouse specific locus test • Dominant lethal test • Transgenic animal tests						
	Chromosomal damage	• Chromosomal aberrations • Micronucleus formation • Sister chromatid exchange • Aneuploidy						
	DNA repair							

HID, highest ineffective dose; LED, lowest effective dose (units as reported); NT, not tested

Table 4 [Genetic and related effects] of [agent] in humans and other mammals in vitro [can also be captured in two separate tables]

Species	Tissue, cell line	End-point	Test	Results	Concentration (LEC or HIC)	Comments	Reference
Human	Liver/HepG2, Prostate/LNCaP, Breast/MCF-7, Lung/A549, Cervical/HeLa, Colon CACO-2, Fibroblasts, Lymphocytes, Hepatocytes, other	DNA damage	• DNA adducts • DNA strand breaks • DNA cross-links • DNA oxidation • Unscheduled DNA synthesis	+ (+) +/– (–) NT			
		Mutation	• Oncogene • Tumour suppressor • Other				
		Chromosomal damage	• Chromosomal aberrations • Micronucleus formation • Sister chromatid exchange • Aneuploidy				
		DNA repair					
		Cell transformation					

Non-human mammalian (e.g. mouse, rat, hamster)	Mouse lymphoma L5178Y, Mouse BALB/c 3T3, Mouse C3H 10T1/2, Mouse primary hepatocyte, Chinese hamster ovary, Chinese hamster lung V79, Syrian hamster, Rat liver RL4, Rat primary hepatocyte, other	DNA damage	• DNA adducts • DNA strand breaks • DNA cross-links • DNA oxidation • Unscheduled DNA synthesis	+ (+) +/– – (–) NT
		Mutation	• *Tk* • *Hprt* • Ouabain resistance • Other genes	
		Chromosomal damage	• Aneuploidy • Chromosomal aberrations • Micronucleus formation • Sister chromatid exchange	
		DNA repair		
		Cell transformation		

HIC, highest ineffective concentration; LEC, lowest effective concentration, NT, not tested

Table 5 [Genetic and related effects] of [agent] in non-mammalian species in vitro

Phylogenetic class	Test system (species, strain)	End-point	Test	Results		Agent, concentration (LEC or HIC)	Comments	Reference
				Without metabolic activation	With metabolic activation			
Acellular systems	DNA, Calf thymus DNA, plasmid DNA, Prophage	DNA damage	• DNA adducts • DNA strand breaks • DNA cross-links • Intercalation • SOS repair test	+ (+) +/– – (–) NT	+ (+) +/– – (–) NT	As reported		
Prokaryote (bacteria)	*Salmonella typhimurium;* TA97, TA98, TA100, TA102, TA104, TA1535, TA1537, TA1538 *Escherichia coli; WP2 uvrA*	Mutation	• Reverse mutation • Forward mutation					
		DNA repair						
Lower eukaryote (yeast, mould, fungi)	*Saccharomyces cerevisiae*, *Schizosaccharomyces pombe, Aspergillus ridulans;, Neurospora crassa*	Mutation	• Reverse mutation • Forward mutation • Gene conversion					

		Chromosomal damage	• Intrachromosomal recombination • Intragenic mitotic recombination • Chromosomal malsegregation	
Insects	*Drosophila melanogaster*	Mutation	• Somatic mutation and recombination test (SMART) • Sex-linked recessive lethal mutations • Heritable translocation test • Dominant-lethal test	NA
		Chromosomal damage	• Aneuploidy	
		DNA repair		
Plant systems	*Vicia faba*	DNA damage	• Unscheduled DNA synthesis	NA
		Mutation		
		Chromosomal damage	• Chromosomal aberrations • Micronucleus formation • Sister chromatid exchange • Aneuploidy	
Other (fish, worm, bird, etc.)	Zebra fish (*Danio rerio*), *Caenorhabditis elegans*, Newt, Seagull	Mutation	• Reverse mutation • Forward mutation	NA

HIC, highest ineffective concentration; LEC, lowest effective concentration, NA, not applicable; NT, not tested